EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

- - -

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE NO. 2:12-MD-02327 MDL 2327
	:	JOSEPH R. GOODWIN
	:	U.S. DISTRICT JUDGE
SHERRY FOX and ROY FOX, JR. Plaintiffs,	:	
v.	:	CASE NO. 2:12-CV-00878
JOHNSON & JOHNSON, INC. and ETHICON, INC., Defendants.	:	

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March 23, 2016

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Oral deposition of KONSTANTIN WALMSLEY, MD taken pursuant to notice, was held at the law offices of Mountainside Hospital, 1 Bay Avenue, Montclair, New Jersey, beginning at 12:23 p.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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I N D E X

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E X H I B I T S

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(Exhibit Fox-Walmsley-4 was retained by the witness and is not attached to the transcript.)

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer

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(Deposition Exhibit No. Fox-Walmsley-1, Amended Notice to take video deposition of Konstantin Walmsley, and Deposition Exhibit No. Fox-Walmsley-2, Rule 26 Expert Report of Konstantin Walmsley, MD, was marked for identification.)

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KONSTANTIN WALMSLEY, MD, after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. OLIVEIRA:

Q. I started to say good morning, Dr. Walmsley, but I realized it's afternoon now. Good afternoon. How are you doing?

A. I'm well.

Q. We met earlier?

A. We did.

Q. I believe I told you I represent Ethicon in this case involving Sherry Fox. And so I guess I'm a little confused, because my

understanding, you're here to offer case-specific opinions today; is that correct?

A. Yes, sir.

Q. Okay. Because I also saw that you had some general opinions in your report?

A. In the Fox report?

Q. Yes.

A. General opinions that are applicable to the case, I suppose, would be the way I would interpret it.

Q. Okay. That's fine.

A. Yeah.

Q. But you're not here to offer -- well, let me ask you this: The general opinions, you say they're related to the facts of this particular case and that's why you've offered them?

A. Yes, sir.

Q. Okay. Let me show you what's been marked as Fox-Walmsley -- I'll just call it Exhibit Number 1. I'm not going to say that every time.

I'll relate to you it's a notice to take your deposition.

Do you see that?

A. Yes, sir.

Q. Have you seen that before?

A. I have.
Q. There's a Document A that's attached to it that has asked you to bring a number of documents.
Did you bring any documents responsive to those?
A. I did.
Q. And what did you bring?
A. I brought -- actually brought Ms. Fox's IME report, and I also brought a list of my prior testimonies.
Q. Had you produced that IME report before? Does your lawyer have a copy?
A. He received a copy yesterday evening. Yes, sir.
Q. Okay. Because I was going to say, I don't think I've seen one. Let's -- I'm sorry.
MR. CASPERSON: We also have some stuff here that -- that's another copy of the IME report, and there's also a thumb drive which has some prior depositions of Dr. Walmsley, some prior reports that he's done in some other pelvic mesh cases, and some invoices, including an invoice for this case.
MR. OLIVEIRA: Okay. I hate these

things because I always lose them.
BY MR. OLIVEIRA:
Q. Well, let's start with the IME report.
Let's mark that as -- I've already got one premarked as 2. So we'll mark that one as 3.
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(Deposition Exhibit No. Fox-Walmsley-3, Fox, Sherry Encounter Summary, 12/04/2015, was marked for identification.)
- - -
BY MR. OLIVEIRA:
Q. And then it looks like you also have a binder --
A. Yes, sir.
Q. -- that you brought.
And can you tell me what's in that binder?
A. This binder is a table of contents, articles and materials that I've relied upon in part to create my opinion. There's some deposition testimony in here as well as medical records. And then some Rule 26 expert reports.

Q. And we'll go ahead and mark that as Exhibit Number 4.

- - -

(Deposition Exhibit No. Fox-Walmsley-4, Binder, was marked for identification.)

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THE WITNESS: I should also mention, if I may, in addition I added some abstracts, three separate abstracts to the binder as well.

BY MR. OLIVEIRA:

Q. And what abstracts are those?

A. These are abstracts that specifically talk to suburethral slings and autologous fascial slings. They're abstracts from three separate articles.

Q. Is this something that you just pulled in the last couple of days, or --

A. In the last week or so as I was getting ready for the deposition, I thought it might be helpful just to look at some of the materials that Dr. Irwin in part relied upon to form her report.

Q. Did you -- you also produced a report in this case?

A. Yes, sir.
Q. I'm going to show you what we'll mark -- that we have marked. It's been marked as Exhibit Number 2 and ask you if that's your report?
A. Yep. This is my report.
Q. When was -- when did you draft that report?
A. Oh, I would reckon two months ago, give or take.
Q. I don't see a date on it.
Do you date your reports?
A. I have in the past. Sometimes I do. Sometimes I do not.
Q. Do you see anywhere in this report where it's been dated?
A. It's not been dated in this report.
Q. And so you say you believe you prepared it two months ago?
A. Yes. Roughly.
Q. Do you have any idea, do you have any indication, any e-mails or anything that would clarify when you sent this report to your attorney?
A. I do, yeah.
Q. You do. Do you have them with you?
A. It's in my computer downstairs. I

can --

Q. On a break I may ask you to go look for the date of -- the date I guess you drafted and the date that you sent it to your lawyer?

A. I'm happy to.

Q. And while you're down there, if you could also do it for the Ridgley case, I would appreciate it.

A. I would be happy to.

Q. There may be a date on that one. I'm not sure there is.

When were you first retained by the plaintiffs to provide or to serve as an expert in this case?

A. In the late summer/early fall of 2015.

Q. And who was it that contacted you?

A. Mr. Casperson.

Q. And what did he ask you to do in this case?

A. He asked me to review medical records relating to the care of Sherry Fox.

Q. And did he send you medical records?

A. Yes, sir.

Q. And do you recall which medical

records those were?

A. They're listed in the report and also in the binder, yes.

Q. Have you ever been retained by Mr. Casperson or his firm in any previous case?

A. I have been, yes.

Q. You have been?

A. Yes, sir.

Q. When was the first time they retained you in a case?

A. 2014.

Q. Was it involving the mesh litigation?

A. Yes, sir.

Q. Do you recall which case it was?

A. One was Boston Scientific, the other is Bard.

Q. No previous Ethicon cases prior to this, these two cases?

A. No, not with Mr. Casperson, no.

Q. How about with any other plaintiffs' firm? Have you been hired by other plaintiffs' firms to provide expert testimony in any mesh cases?

A. I have, yes.

Q. What other firms are you dealing with right now?

A. There's one case relating to a Prolift case. That was actually a med mal case. And then I also served as an expert witness for Boston Scientific and Bard for Perdue & Kidd.

Q. When you say you served as an expert for Boston Scientific, you weren't retained by Boston Scientific. Correct?

A. No, sir. I was retained -- it was in that litigation.

Q. But you were retained by the Perdue firm from Houston?

A. Yes, sir.

Q. What was the first year, I guess, when were you first retained to do any -- provide any expert testimony in any of these mesh cases?

A. That would be 2013.

Q. Do you know how many cases, mesh cases, you've been retained on to date?

A. I would give a fairly reliable estimate of eight to ten.

Q. Do you think it could be more?

A. No.

Q. Do you know how much you've billed in all those cases?

A. All combined?

Q. Yes.
A. Probably in the order of 50- to $75,000.
Q. You said you generated an invoice, and I got your attorney handing me a thumb drive, and I can't open it right now.
But do you know how much you've billed on the Fox case?
A. I'd have to give you a ballpark estimate, in the range of 6- to $7,000.
Q. And how many hours does that involve?
A. That involves about 13 hours, 13-plus hours of work.
Q. Does that include preparation for this depo?
A. No. No, sir.
Q. How much time have you spent preparing for this deposition today?
A. I received some -- well, I reviewed Irwin's report, and I also reviewed some additional records, so probably in the order of four to six hours. I have it written down, but I haven't billed yet for this.
Q. Have you -- prior to I guess providing expert testimony in the mesh cases, and I

think you told us about one malpractice case, have you served as an expert before in other litigation?

A. I have, yes, sir.

Q. About how many cases?

A. I'd guess I'd have to ask, when you say serving as an expert witness, are you speaking in terms of these going to testimony or just all the cases I've given --

Q. Just where you've been retained to provide expert testimony.

A. I probably review -- as far as giving prior testimony, probably in the order of 15 to 20.

Q. And how many times have you been deposed?

A. As an expert witness, I've been deposed perhaps ten times.

Q. So then -- and I forgot to bring this up in the beginning. So then you know the basic rules of a deposition. We have this lovely young lady over here taking down everything we say, and if we speak over each other, we'll drive her crazy. So I'll do my best not to interrupt you, and if you can wait until I finish my question, it will help her out a lot.

A. Yes, sir.

Q. Okay. Thanks. And you you've done fine so far. It's something I neglected to say earlier.

If you can turn to your report, which is Exhibit Number 2, I believe.

You have that in front of you?

A. Yes.

Q. Did you include all of your opinions in this report that you intend to testify about in this case?

A. Yes.

Q. Okay. And as you sit here today, have you received any additional information that you didn't have when you prepared this report?

A. Yes.

Q. And what additional information is that?

A. Some additional medical records relating to physical therapy received by the patient and some additional depositions, one of Dr. Irwin's and the other, Dr. Thames.

Q. What deposition did you see of Dr. Irwin's?

A. Dr. Irwin provide -- I'm sorry. It wasn't a deposition. Excuse me. It was a Rule 26

report. Pardon. As was Dr. Thames a Rule 26 report.

Q. Was it a Rule 26 report regarding this case, regarding the Fox case?

A. Yes.

Q. And you received those all after you did your report?

A. Yes.

Q. Now that you've gotten this additional -- and let me ask you, is there any other additional information that you've gotten that you didn't have when you drafted this report?

A. No.

Q. Is any of this additional information, is that going to require you to supplement your report or revise your report in any way?

A. No.

Q. I believe you just told me you performed a physical examination of Mrs. Fox in this case?

A. Yes, sir, I did.

Q. And when did that take place?

A. That occurred on December 4, 2015.

Q. Did you request that?

A. Mr. Casperson requested that.
Q. And where did you examine her?
A. I examined her in my office.
Q. Your office here in New Jersey?
A. Yes, sir.
Q. So she flew up to -- for that visit?
A. Yes.
Q. Let me ask you, other than -- well, strike that.

Let me ask you, what did you review before drafting your report, your final report? What did you rely on to draft your report?

A. So I relied upon the medical records that are stated in the report. There were a handful of articles that I used as references in terms of forming my opinion. I had the IFU for the TVT device that dated back to the time that it was implanted. And also an informed consent document produced by the AMA.

There were several depositions that I relied upon, that of Mrs. Fox, Dr. Warner, Dr. Villa-Olvera, Dr. Haverkorn and then of course my IME as well.

Q. And the medical records that you said you've relied on, are all those contained in the

binder that's been marked as -- I believe as -- did we mark them Exhibit 4, I believe?

A. Yes. And the answer to that is yes.

Q. How many studies did you rely on?

A. Many.

Q. They're all listed there? Do you have them numbered or --

A. They're all -- they're all provided here numerically and with a bibliography, and there are a total of over 20 of them.

And I guess as we were alluding to before, this is a case-specific report. I've read hundreds of articles that relate to pelvic mesh and -- both in the world of slings and pelvic organ prolapse repair. But these were the ones of significance that I really relied upon in the formation of my opinion here.

Q. And I'm looking at your binder, and it looks like it has 34 tabs in it?

A. Correct. Yeah.

Q. Besides -- is each one tabbed separately, or are they --

A. The articles are all tabbed separately, and the articles run from tab 3 to tab 22.

Q. And then after tab 22, do you have an index there?

A. Yes, sir.

After tab 22, there are four depositions, 23 to 26. The medical records encompass tabs 27 to tab 31. And then there are three additional documents, two Rule 26 expert reports that I alluded to before, and then 34 is photos of the pathology specimen from Mrs. Fox's mesh explant.

Q. Is there anything other than what you've showed us in your binders, anything -- and then I guess the IME report, is there anything else that you relied on in formulating your opinions for your report?

A. No, sir.

MR. CASPERSON: Objection to form.

BY MR. OLIVEIRA:

Q. Have you ever implanted midurethral slings in patients?

A. I have, yes.

Q. Do you know how many?

A. I could give you a ballpark estimate. I've been in practice since 2004. Between 2003 and 2004, during my fellowship, I implanted roughly 50

implants. And then in practice, I implanted -- during the early part of my career, I probably implanted between 30 and 40 implants a year. Now I'm implanting about 20 or so per year. So I would give an estimate of several hundred. I mean, certainly over 250 and probably more on the order of 300 to 400.

Q. Okay. Have you ever implanted a TVT device like the one that was implanted in Mrs. Fox in this case?

A. I have.

Q. And when did you -- when was the last time that you did one of those?

A. Primarily during my fellowship years.

Q. And did you receive training, I guess, from Ethicon, some kind of training before you began implanting their products?

A. Actually, most of my training occurred both during my residency and then in my fellowship with a Dr. Steven Kaplan.

I did receive training in private practice on the TVT SECUR device. But as far as the classic TVT device, I learned primarily during my training years.

Q. And you say you still implant

midurethral slings?

A. I do.

Q. And 20 to 25 a year?

A. Roughly, yes.

Q. Do any of those include Ethicon products or --

A. No. No, sir.

Q. What primarily, what products do you use?

A. Three main products, a Bard product, a Coloplast product and occasionally an AMS product.

Q. Have you ever taken a part or have you ever done any studies yourself involving the treatment of stress urinary incontinence surgically or the surgical treatment, I guess, of stress urinary incontinence?

A. I've not published any articles in that arena, no.

Q. How about any studies involving the TVT product that was used in this case?

A. No, sir.

Q. I looked at your reliance list or the studies I guess that you looked at earlier. And one of the studies I noticed you listed in your list is the Nilsson study?

A. Yes.
Q. And that was a study done by Dr. Nilsson in 2013. Correct?
A. Yes, sir.
Q. And it's called the "Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence"?
A. Yes.
Q. And it looks like, since you listed it, I assume, then, that you considered that as part of your -- considered that study in formulating your opinions in this case?
A. Yes.
Q. That study, you would agree with me that study was done by a reputable author in a peer-referenced journal. Correct?
MR. CASPERSON: Form.
THE WITNESS: Yes.
BY MR. OLIVEIRA:
Q. And did you review any other studies that showed that polypropylene-based midurethral slings like the TVT have low compliance -- or low complications rate?
Let me rephrase that because I kind of jumped ahead.

A. Uh-huh.

Q. This study I guess shows -- the results were that it showed that polypropylene-based midurethral slings had low complications rate. Correct?

A. The Nilsson study did demonstrate a fairly low complication rate.

Q. And they showed that they were safe and reliable?

MR. CASPERSON: Form.

THE WITNESS: I mean, those terms were not used in the report, but his conclusion was that it was a durable procedure with a high satisfaction rate.

BY MR. OLIVEIRA:

Q. When you said a low complications rate, do you remember what the complications rate was? Or do you have that in front of you?

A. Well, of his report, a little under 80 percent were reachable via telephone interview. So it's -- you know, given the fact that over 20 percent were not really followed up on, I think that's a fair critique of the follow-up. These were retrospective phone-based interviews of which only half the patients were visiting the clinic. So the

20 of them, over 20 were lost to follow-up. 12 were interviewed via phone. So, in essence, only half the patients really were examined in a comprehensive enough fashion that I think that that would be a way to really look at complications.

MR. OLIVEIRA: Objection, form.

BY MR. OLIVEIRA:

Q. My question is, what was the complication rate? What was the rate, the result that they reached that this study showed?

MR. CASPERSON: Object to the form of the question.

THE WITNESS: You know, this report didn't necessarily look at complications as much as success or cure rates, to my mind. So it's hard to answer that question.

BY MR. OLIVEIRA:

Q. So let me ask you this.

A. Yes.

Q. What was the success rate, I guess?

A. He -- the conclusion was that over 90 percent of the women were objectively continent, and 87 percent were significantly cured or improved of the patients who were available to be questioned.

Q. Doctor, would you agree with me that

stress urinary incontinence is a life -- or can be a life-altering condition for women?

A. Yes.

Q. And for many women with this condition, it can seriously restrict their everyday activities?

A. Yes.

Q. Exercising, working, if it's serious enough. Correct?

A. I agree.

Q. And I think you testified previously in other cases that polypropylene mesh -- polypropylene-based mesh slings like the TVT are the standard of care for midurethral slings. Correct? Do you recall that?

A. I recall saying something to that effect.

Q. Do you recall also saying previously that polypropylene slings like the TVT are the gold standard for surgical treatment of SUI?

A. No. That I specifically recall refuting, actually.

Q. Okay. So you don't think you said that in a previous deposition?

A. If I did, I think what I was probably

alluding to was the fact that they're still done. And for most of us, it is considered the standard of care. But I recall, frankly, disputing the concept of gold standard.

Q. Fair enough. In 2002 when Mrs. Fox had a TVT implanted to treat SUI, would you agree at that time it was the standard of care for surgical treatment of SUI?

MR. CASPERSON: Objection to form.

THE WITNESS: No, I would not.

BY MR. OLIVEIRA:

Q. In 2002 it would not be the standard of care?

A. Not in my practice and training at that time.

Q. Can you cite me to I guess any studies that would say -- that would show that it was not considered the standard of care in 2002 when Mrs. Fox had hers implanted?

A. I could.

Q. And what studies are those?

A. Part of my training at Cornell involved mentorship under a Jerry Blaivas, who is a major proponent of the autologous fascial sling.

In 2002, over 80 percent of the

slings that I implanted were of the autologous fascial variety. Dr. Blaivas, even as late as 2011, has published articles in which he opines that the autologous fascial sling is the gold standard of care for the treatment of stress urinary incontinence.

MR. OLIVEIRA: Object to form.

BY MR. OLIVEIRA:

Q. But my question was when Mrs. Fox had this implanted in 2002, would the TVT that was implanted, would it be considered the standard of care -- I didn't say the gold standard -- for surgical treatment of SUI?

A. No.

Q. And you believe, then, that the implanting physician, then, violated the standard of care by implanting that device in 2002?

A. No. I wouldn't say that.

Q. Okay. Then how do you recognize that you -- when you make the statement that it was not the standard of care?

A. I would reconcile that by stating that oftentimes we provide surgical care where we utilize techniques or devices that may not necessarily be recognized as either the standard of

care or the gold standard of care.

Q. But your position as you sit here today is that in 2002, implanting the TVT device would not have been the standard of care?

A. Not yet.

Q. When did it become the standard of care?

A. That's a difficult question to ask, but I would opine that it became the standard of care probably in the latter part of the first decade of the 21st century, in the 2005 to 2007 arena.

Q. Were people -- I mean, were gynecologists and urogynecologists implanting -- obviously there were people implanting midurethral slings prior to that time. Correct?

A. Urologists too, yes.

Q. Okay. And so it was an acceptable procedure prior to 2005-2006?

A. Yes.

Q. And it was one that was used widely in your profession for the treatment of SUI?

A. Starting to at that time, yes.

Q. Mark the next exhibit.

- - -

(Deposition Exhibit No.

Fox-Walmsley-5, AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence, was marked for identification.)

- - -

BY MR. OLIVEIRA:

Q. I'm going to hand you Exhibit Number 5, which I will tell you is the AUGS and SUFU position statement on mesh midurethral slings for stress urinary incontinence.

A. Thank you.

Q. Are you familiar with this statement?

A. I am.

Q. And so the jury's clear, SUI -- or AUGS stands for Advanced -- I'm sorry, the Association of Urogynecologists Society? Or is that right? Or Advanced Urogynecology --

A. I think it's the Association of Urogynecological Surgeons.

Q. Surgeons. Thank you.

A. Yes, sir.

Q. And then is SUFU it looks like is the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction; is that correct?

A. Yes, sir.

Q. And are these two reputable, recognized societies?

A. Yes, sir.

Q. The top statement in the paper -- let me see where I can find this. My other copy had it highlighted.

There's a portion in there, I'll read it to you, it says, "The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of SUI."

It goes on to say, "The procedure is safe, effective, and has improved the quality of life for millions of women."

MR. CASPERSON: Is it under conclusions?

MR. OLIVEIRA: It might be. Let me see.

THE WITNESS: Yes.

BY MR. OLIVEIRA:

Q. Did you find it?

A. Yes. It's in two separate locations, but yes.

Q. Where is the first location that you find it?

A. Page 2, bold, bold number 3, it

states, "Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI."

And then your other comment is the first page -- is the first sentence of the conclusion section on page 3.

MR. OLIVEIRA: Okay. Let's go off the record for a second.

MR. CASPERSON: Okay. Off the record.

- - -

(A recess was taken from 12:53 p.m. to 12:54 p.m.)

- - -

BY MR. OLIVEIRA:

Q. So, Doctor, I think when we were -- when I previously asked you about that statement, you said I guess you found it on page 2 and it looks like on number 3?

A. Yes.

Q. So it says, "Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients."

Do you agree with that statement?

MR. CASPERSON: Form.

THE WITNESS: I think in part I do, yes.

BY MR. OLIVEIRA:

Q. And then I think the second part that talks about the procedure is safe -- well, let me ask you this because you said in part. I should ask you.

A. Yeah.

Q. What part do you not agree with?

A. I think it's become the standard of care for the surgical treatment of SUI. I think it is a mild to moderate advance in the treatment of this condition for our patients, in part because it has shown -- certain elements have been shown to be superior to the other treatments that we offer. However, there are potential complications that can arise from the use of mesh for pelvic slings -- or for urethral slings, excuse me.

Q. Doctor, isn't it true there's also complications with nonmesh procedures for the treatment of SUI?

A. Yes. Certainly.

Q. I think the second part says, "The

procedure is safe, effective and has improved the... life for millions of women."

And you said you found that I guess on the third page or --

A. On the third page, the first sentence of the conclusion states it has helped millions of women, although I don't see the safe, effective part of that comment.

Q. I think the next sentence has it, where it says "acknowledged safety and efficacy it has created in an environment for a much larger number of women."

A. Right.

Q. My question is, do you agree with that statement?

MR. CASPERSON: Objection, form.

THE WITNESS: I don't.

BY MR. OLIVEIRA:

Q. And why don't you agree with that statement?

A. You know, in part because there are questions as to the safety of slings and because the efficacy over longer periods of time isn't necessarily as high as one would expect it to be, certainly, for example, to call it a gold standard

type of procedure.

Q. What about the Nilsson 17-year study that we talked about earlier? Doesn't that show that over a long period of time, it was effective?

A. I think in his study, of 50 percent or so of patients that he actually was able to have physical contact with, it showed a high rate of success.

Q. Well, you gave me your reasons I guess why you question the safety and efficacy, but the first statement, it says it "has helped millions of women with SUI regain control of their lives."

Would you agree with that?

A. I think that's a true comment, yes.

Q. Let's look at, I guess, the second page now.

The first statement says, "Polypropylene material is safe and effective as a surgical implant."

Do you agree with that statement?

MR. CASPERSON: Objection, form.

THE WITNESS: Is that comment number 2?

BY MR. OLIVEIRA:

Q. I think it's number 1.

"Polypropylene material is safe and effective as a surgical implant."

A. Yes. I think that's a nebulous statement, so I think it could be worded differently.

Q. Worded as is, would you agree with that?

A. I would say polypropylene material is safe and effective as a surgical implant for the repair of hernias, for example, for example, for the repair of abdominal wall hernias or for an application in sacrocolpopexy, but I would question that comment in the context of pelvic mesh.

Q. You've told us you continue to use polypropylene materials in the treatment of SUI, and you continue to implant them. Correct?

A. This is true.

Q. And so you do that even though you're questioning the safety and effectiveness of it?

A. You know, in 2016, I'm able to counsel my patients differently about sling surgery. And there's a reason I implant less slings than I did five, ten years ago.

Q. But you still implant them?

A. I do.

Q. And you haven't quit implanting surgical mesh, have you?
A. I have not, no.
Q. What about, do you agree that -- well, let me ask you this: You do implant polypropylene materials -- you currently still do it, so would you agree with me, then, that you wouldn't do it if it wasn't a safe and effective alternative for the treatment of SUI, would you?
MR. CASPERSON: Objection, form.
THE WITNESS: I'm sorry. Could you rephrase that question? I'm sorry.
BY MR. OLIVEIRA:
Q. No, it's okay. It's my fault.
You've told us that you still implant polypropylene mesh. And so is it fair to say, then, that you believe that it's safe for your patients to have these implants and that it is safe -- that it's effective for the treatment of SUI?
A. I believe that it's -- after an informed consent has been given for some of my patients, it's a safer and more effective form than other treatments.
Q. And then number 3 says, "Polypropylene mesh midurethral slings are the

standard of care for the surgical treatment of SUI and represents a great" advantage "in the treatment of this condition for our patients."

Do you see that?

A. I do.

Q. And do you agree with that statement?

MR. CASPERSON: Objection, form.

THE WITNESS: It says "great advance" instead of "advantage."

BY MR. OLIVEIRA:

Q. I'm sorry.

A. I think I answered the question before that I didn't agree with it in whole.

Q. And remind me again what your -- what you disagreed with.

A. My comment is that -- my comment before was that I felt that it was -- the terminology "great advance" I think kind of overstates the utility of slings, and certainly in the armamentarium to treat stress urinary incontinence, it's become a very commonly utilized procedure. Whether it's truly a great advance in the treatment of this condition, I think to some degree remains to be seen.

Q. Have you ever belonged to AUGS or

SUFU?

A. I've not.

Q. Do you practice with other urogynecologists or urologists who belong to either of those organizations?

A. I do.

Q. Are you familiar also with the American Urogynecological Association, the AUA, position statement on the use of vaginal mesh for surgical treatment of SUI?

A. I've seen it before.

Q. And I think -- and I don't have a copy of that, but do you agree with the statement it makes in there that extensive data exists to support the use of polypropylene mesh suburethral slings for the treatment of female SUI with minimal morbidity compared to alternative surgeries?

MR. CASPERSON: Objection to form.

THE WITNESS: I agree for the most part with the exception of the minimal morbidity.

BY MR. OLIVEIRA:

Q. So you disagree that there's minimal morbidity?

A. I think the morbidity occurs in a small subset of patients; however, that morbidity

can be more than minimal for those patients.

Q. It goes on to say that advantages include shorter operation time. I'll break it down so that I can give you a chance to...

Do you agree with the statement that one of the advantages include a shorter operation time?

A. Yes, sir.

Q. I guess reduced surgical pain?

MR. CASPERSON: Objection, form.

THE WITNESS: Not necessarily, but possibly.

BY MR. OLIVEIRA:

Q. Reduced hospitalization?

MR. CASPERSON: Objection, form.

THE WITNESS: Yes.

BY MR. OLIVEIRA:

Q. And then I guess another advantage they list is voiding dysfunction?

MR. CASPERSON: Objection to form.

BY MR. OLIVEIRA:

Q. Reduced voiding dysfunction I guess would be --

A. In the short term, yes. In the long term, no.

Q. It goes on to say, mesh-related complications can occur following polypropylene sling replacement, but the rate of complications is acceptably low.

Do you agree with that statement?

MR. CASPERSON: Objection, form.

THE WITNESS: I think from a quantitative statement, that's a true comment.

MR. OLIVEIRA: Doctor, if you don't mind, let's take a little break, and we'll move into phase 2.

THE WITNESS: Thank you.

- - -

(A recess was taken from 1:04 p.m. to 1:21 p.m.)

- - -

BY MR. OLIVEIRA:

Q. If you could I'd ask you to turn to your report, which we have marked as -- I believe as Exhibit 2 in this case.

A. Yep.

Q. It looks like the first four or five pages of your report are kind of background information and mentions, I guess, the medical records and depositions that you reviewed, along

with the medical literature and other documents that you reviewed. Correct?

A. Yes.

Q. And then you do -- at some point you have a clinical history where you -- it looks like a little chronology where you list a number of different things in her medical history, I guess, that you believe were significant?

A. Yes, sir.

Q. Then after that, you get into what looks like the couple of general opinions?

A. Yes, sir.

Q. And then five case-specific opinions or -- yes, it looks like it's five. Is that correct?

A. Yes.

Q. So let me ask you about your first opinion.

Your first general opinion, you state there at the bottom that it's your opinion "the IFU for the TVT in 2002 was not sufficient to enable informed consent from the patient."

What do you base that on?

A. I base that on my clinical experience with TVT and, for that matter, other polypropylene

mesh slings and the IFU that I reviewed that dated back to the time when this sling was implanted.

Q. And what do you believe is missing from this IFU that you would put in it?

A. Well, there are a lot of potential complications that were not mentioned in the IFU that I've listed in my report.

Q. Doctor, would you agree with me that generally, that IFUs typically don't include every potential adverse reaction or complication? Isn't that correct?

A. Not necessarily.

Q. So you believe that they should have every adverse reaction or every possible reaction to the product?

A. I think they should have the majority of them, the ones that are the most likely to occur.

For those that are case-report like complications or case-report like findings, I would agree with you, those don't necessarily need to be in the IFU. But certainly the ones that you see with even some regularity or occasional regularity should be mentioned.

Q. So tell me, then, which ones do you believe should be in there?

A. Well, first, as far as complications to be mentioned, mesh contraction would be one. Dyspareunia. Mesh shrinkage. Scar plate formation. The difficulty in removing mesh.

Q. Are those all the ones you feel should be in there?

A. That's the majority of them, yes.

Q. You would agree with me that a doctor not only has to rely on the IFU for explaining, I guess, the adverse reactions and possible side effects to a plaintiff.

Would you agree with that?

A. I'm sorry. Could you repeat that question?

Q. Well, can doctors also rely, don't they also rely on their experience, their clinical experience in implanting mesh or in this particular case, to rely on -- in providing an informed consent to the plaintiff?

A. I think that's a true comment, yes.

Q. And do you do that in your practice?

A. I do.

Q. And do you include things when you go over your informed consent that are not necessarily included in the IFU?

A. To some degree.

Q. Do you believe that most doctors do that?

A. Well, it's hard for me to comment on that. I'm not necessarily sure what all doctors do, but I think that's the standard of care.

Q. The standard of care is that they should --

Well, let me ask you this: Is it your understanding -- is the IFU intended to be a substitute for a surgeon's knowledge or expertise in a case?

A. In terms of providing clinical consent you mean?

Q. Yes.

A. No. I think there are two elements to the informed consent: One provided by the IFU, and to your point, I think the other provided by a surgeon's experience, assuming he or she has clinical experience.

Q. And the IFU is not intended to be a substitute for a surgeon's responsibility to adequately counsel a patient regarding the risk and benefits of treatment options. Correct?

A. I don't think it's a substitute, but

I think it's something that's a necessary adjunct. I mean, for example, for someone who's performing their first 10 to 15 slings, I would imagine those individuals would rely in large part on the IFU to counsel patients appropriately.

Q. But wouldn't they also rely on any training they received?

A. True.

Q. And wouldn't most people, most doctors that are doing those first 10 or 15 slings would have learned from somebody else or would have been trained by somebody else prior to them inserting or implanting those slings. Correct?

A. I would hope so.

Q. I lost my place in your report.

And then in general opinion number 2, it looks like you're -- what is your general opinion number 2? I'm not sure --

A. General opinion number 2 is that "Safer alternatives designs and procedures existed in 2002 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy."

Q. Which procedures in particular are you referring to?

A. The autologous fascial sling.

Q. What else?
A. Primarily that procedure in my experience, but certainly nonsynthetic mesh-based repairs were alternatives.
Q. But the autologous procedure doesn't come without risk either, does it?
A. That's correct.
Q. I mean, it has risks?
A. That's correct.
Q. And it has complications?
A. True.
Q. And hasn't it also proven to be less effective than midurethral slings in treating stress urinary incontinence?
A. Not in my practice, no.
Q. Have you seen studies that indicate that midurethral slings have a higher success rate in treating stress urinary incontinence?
A. I've seen some studies that provide that opinion.
Q. What else do you -- you say "safer alternatives designs and procedures existed in 2002."
Other than the autologous sling that you told us about, what else existed back then?

A. There were biological graft slings that were available at that time using porcine dermis, for example. The Burch colposuspension procedure was available.

Q. Have you ever used any of those procedures?

A. I have. Not -- well, let me amend that. The Burch colposuspension procedure I did in my training, but I did not utilize that in my private practice.

Q. Why is that?

A. You know, because I started utilizing the autologous fascial sling at the tail end of my training, and that replaced my utilization of the Burch colposuspension procedure.

Q. And what other -- and you mentioned, I guess -- what was the other procedure that you mentioned was safer?

A. The use of a biological graft sling using basically porcine dermis, pigskin.

Q. Did you ever use that in your practice?

A. I did.

Q. Do you use it?

A. I don't use it any more because it's

not marketed anymore, in fact.

Q. When was the last time you used that?

A. 2008, 2009, in that range.

Q. Let me ask you, also you say "safer alternatives designs."

You're not going to offer any opinions here today on -- you're not being offered as a design expert, are you?

A. I'm not, no.

Q. Okay. And so other than these procedures that you just listed, what other procedure have you not told us about that is safer?

A. Well, one procedure that would be safer would involve urethral bulking, the use of either collagen or another substance to bulk up the external sphincter of the female urethra.

Q. Do you use that procedure?

A. Occasionally I do.

Q. Do you use it in your practice today?

A. I do.

Q. Anything else you haven't told us about?

A. With regards to what I was using back in 2002, no.

Q. And those are all the general

opinions that you've given that relate to, I guess, Mrs. Fox in this case, just those two?

A. The only one other thing I think is worth mentioning is -- dates back -- or goes back to the general opinion number 1 with regards to the IFU, which is the, in my opinion, inappropriate use of the term "transitory."

Q. And why is it inappropriate?

A. Because in the 2000 -- in the IFU that would have been available in 2002, the word "transitory" was used in two contexts, one being "transitory local irritation at the wound site" and the next being "transitory foreign body response may occur."

And as stated in the report, the use of transitory really defines a condition that is temporary, when, in fact, a thing such as foreign body response and irritation at the wound site are quite the contrary. They're chronic events.

Q. And so you would disagree with that because of the reasons you just stated?

A. Yes, sir.

Q. Anything else with regards to number 1, general opinion number 1?

A. No, sir. That's it.

Q. Then we go to your case-specific opinions, and your first one is that "Mrs. Fox suffered vaginal sling extrusion, contraction, scar plate formation, and failure of the TVT to incorporate, as a result of the physical properties of the TVT device."

Let's start with the first one.

A. Okay.

Q. How did you determine she had extrusion?

A. Based on my review of the medical records, and to some degree the deposition of Dr. Olvera specifically.

Q. And what in particular did you see in Dr. Olvera's report that led you to believe there was extrusion?

A. She describes an edge of the TVT located near the urethra that she specifies as an erosion.

Q. Anything else that supports your belief that there was an extrusion?

A. Other than her identifying mesh within the vagina, no.

Q. Did you see any evidence of erosion in any medical records?

MR. CASPERSON: Object to the form.

Let me clarify the basis. Because the records go back and forth, I think we need to clarify that for the record, which is which.

THE WITNESS: I mean, I think -- yeah. I think of erosion and extrusion as occurring along a continuum. There are some doctors that believe that erosion really specifies mesh eroding into an organ, for example, the bladder or the rectum. There are others that would identify exposure, if you will, of mesh into the vagina as an extrusion event. I think an extrusion is a minor erosion. And an erosion is a major extrusion, if you will.

BY MR. OLIVEIRA:

Q. Okay.

A. So I think of them as really one and the same with an extrusion essentially being a minor erosion event.

Q. My question, I guess, is, do you see in any of her medical records where any of her doctors said there was an erosion -- they described it as an erosion as opposed to an extrusion?

A. The doctor says two different things. Dr. Haverkorn uses extrusion more commonly, and

Dr. Olvera initially states an erosion of the edge of the TVT near the urethra when, in fact, I think it's semantically one and the same.

Q. So your belief it's one and the same, but you recognize that some urologists/urogynecologists believe there is a difference, and some doctors believe there is a difference?

A. I think that's a fair comment.

Q. Let's go on, because you've got some other -- we've just covered extrusion.

You also mention contraction.

A. Yes, sir.

Q. What's your basis for finding contraction?

A. I think mesh contraction in the case of Sherry Fox was primarily identified not only by her clinical course but also by Dr. Haverkorn's findings.

Q. That mesh contraction was?

A. Correct.

Q. And that Dr. Haverkorn, you're saying in her findings and her report, found mesh contraction?

A. I think her medical records indicated

that, and then she supported that in her deposition.

Q. Do you have that in front of you, where she says that mesh contraction?

A. Yes. It's at the bottom of where you see my specific opinion on contraction and shrinkage. I state that "Mrs. Fox's TVT contracted post implantation. Dr. Haverkorn testified generally regarding mesh contraction or shrinkage as follows," where she's asked in her deposition about mesh shrinkage. And she describes mesh shrinkage as something that occurs.

Q. Something that occurs, but does she say that it occurred in Mrs. Fox?

A. She does.

Q. Okay.

A. Yeah, on page 40 of her deposition, there is language that supports that concept where the mesh was present and was taut.

Q. What about on the -- you also in your case-specific, you mentioned the failure of the TVT to incorporate.

A. Correct.

Q. On what basis do you make that statement?

A. Primarily on the basis of there being

a mesh erosion or extrusion, as the case may be, where de facto one is seeing a piece of mesh that is not incorporated into the host tissues.

Dr. Villa-Olvera in her records visually, but also in her deposition, describes clear white mesh on the surface of the vagina that was not incorporated into any of the host tissues, Mrs. Fox's vaginal tissues specifically.

Q. And I'm sorry. She says that in her deposition?

A. Yes, sir.

Q. Can you point that out to me? Is that something that you've listed in your report --

A. It's in my report under "D. Failure to Incorporate." And that is further along, I think, where you're looking at currently.

After the picture of the removed portion of the TVT mesh, there's comments related to the deposition.

Q. Okay.

A. Yes, sir.

Q. Okay. Where she describes it as not being incorporated into the --

A. Yeah.

Q. Okay. Anywhere else that you saw

that?

A. Other than the medical records and what was stated in the deposition, no.

Well, I shouldn't say that. I stand corrected. Dr. Haverkorn's operative report speaks to a mesh exposure which would support a failure to incorporate.

Q. Let's turn to your case-specific opinion number 2.

You state, "Mrs. Fox's extrusion in 2012 was caused by the physical properties of the TVT -- specifically, the mechanically cut edge of the TVT."

What do you mean -- what do you mean there? What's your basis for saying that?

A. My basis for saying that, at least from a case-specific standpoint, speaks to the nature of her extrusion/erosion, namely, the fact that the mesh extrusion or erosion, if you will, occurred at the edge of the TVT sling.

In addition, I do have some understanding based on my training and experience that there is a difference between -- there's a difference in terms of causes of exposure or erosion. For example, occasionally I've seen mesh

erosion or extrusion events occur in the context of a fraying or roping of the mesh. So at the time of surgery, I'll find that myself.

In this particular instance, given the location of the erosion, it being at the edge, I would conclude it was based on the mechanically cut edge of the TVT.

MR. OLIVEIRA: Object to the form.

BY MR. OLIVEIRA:

Q. Did you see any evidence of degradation of the mesh or have you seen any evidence anywhere in any of the reports of degradation of the mesh or...

MR. CASPERSON: Object to the form.

THE WITNESS: Not in Mrs. Fox's case I did not.

BY MR. OLIVEIRA:

Q. Any evidence of chronic inflammation?

A. I believe so, yes.

Q. Where did you see that?

A. Well, I think the premise to this answer lies in the fact that when a suburethral polypropylene sling is placed, part of the properties of its success, if you will, delve into a chronic inflammatory process whereby a scar plate is

generated that allows the mesh to have or provide a backboard of support to prevent incontinence.

Certainly looking at the picture of the mesh explant, there's a significant amount of fibrotic tissue in addition to the exposed part of the mesh that would support the concept of chronic inflammation.

Q. Did you consider vaginal atrophy as a possible cause of Mrs. Fox's extrusion in 2012?

A. I did.

Q. And did you rule that out?

A. Yes, sir, I did.

Q. Is vaginal atrophy something that could cause or lead mesh to extrude in a patient?

A. It could certainly increase the complication of that, yes.

Q. And then your case-specific opinion number 3 is that her "vaginal pain and dyspareunia (from July 2011 to March 2012) was caused by her sling extrusion, contraction of the TVT device, and scar plate formation."

Is that your third opinion?

A. Yes, sir.

Q. Isn't it true that dyspareunia and pain following TVT surgery are pretty uncommon?

MR. CASPERSON: Objection, form.
THE WITNESS: They're fairly uncommon.
BY MR. OLIVEIRA:
Q. Have you seen the Tommaselli 2015 systematic review and analysis?
A. Is this the Cochran review that you're referring to?
Q. I think this one was Tommaselli. I'm not sure if Cochran was a co-author, but it's a 2015 -- I'll tell you this: This study found that only 13 patients out of 3,974 who had had suburethral slings implanted had persistent or chronic pain.
Have you seen that study?
A. I may be aware of that study, but off the top of my head, I'm not fully aware of it.
Q. And I'll tell you, it was only 13 out of 3,974 patients, and that's a rate of 0.3 percent.
Would you agree that's a pretty low rate of dyspareunia and pain following TVT surgery?
MR. CASPERSON: Objection, form.
THE WITNESS: Based on his experience, that's certainly lower than what I see in my practice and what I would counsel patients

towards.
BY MR. OLIVEIRA:
Q. Can you point me to any studies that you've done that would -- that you conducted yourself that would show a higher rate?
A. Well, my experience is just based on my clinical practice using TVT.
Q. But you haven't published any studies or you haven't conducted any level 1 -- or you haven't taken part in any level 1 studies that studied this issue, have you?
A. I've not.
Q. Okay.
A. I'm not fully familiar with the study that you've quoted to me, but...
Q. What is Lichens sclerosis?
A. Well, Lichens sclerosis is a dermatological condition that entails the development of whitish plaques that can typically cause an itching type of a discomfort on the external genitalia amongst other locations.
Q. Is it something that can become a serious problem for women?
A. It can become a serious problem for women and men.

Q. For men too?
A. Yeah.
Q. Is that something that could be responsible for or could cause the uncomfortableness that Mrs. Fox notes, I guess, in sitting down for periods of time? Could that be a reason?
A. That is sometimes described as being an issue for Lichens sclerosis, yeah.
Q. Is Lichens sclerosis, isn't one of the side effects also dyspareunia?
A. There are instances where there is external dyspareunia with Lichens sclerosis, yes.
Q. What about her diagnosis of superimposed vulvodynia, are you familiar with that?
MR. CASPERSON: Objection.
THE WITNESS: Yes.
BY MR. OLIVEIRA:
Q. Did you consider that in considering her vaginal pain and dyspareunia?
A. I did, yes, sir.
Q. And did you rule that out also?
A. I did, yes, sir.
Q. Let's go to your case-specific opinion number 4.
It looks like your opinion there is

that she "continues to have dyspareunia presently"?

A. Correct.

Q. And what do you base that on?

A. In large part on my independent exam, but also based on -- well, I should say because of presently, I would say it's in large part on the basis of my medical exam which was performed on December 4, 2015.

Q. And this is the report that you handed me earlier that, I guess, we've marked as Exhibit Number 3, it looks like?

A. Yes.

Q. What was the result of that exam? What did you find?

A. Well, in part, besides taking a clinical history during which time she explained to me that she had dyspareunia, on questioning her and talking about the type of dyspareunia she had, she related her dyspareunia to in part being an internal dyspareunia, where on exam I could palpably reproduce pain upon palpation somewhat deep in the vagina but up in what's called the right vaginal sulcus of the vagina, which is the location of her -- near the location of her erosion event or extrusion event, as the case may be.

Q. What else in her physical exam led you to believe she continues to have dyspareunia?

A. I think to be fair, you know, we have to premise the answer or I have to premise the answer by saying dyspareunia, which is discomfort with intimacy, is premised on attempts at intimacy. And to be fair, because of her dyspareunia, she's only attempting to have intercourse on a somewhat infrequent basis.

That being said, in discussing with her her dyspareunia, she attributes the dyspareunia to a specific location within her vaginal area.

On my exam, when I examined her, at least, her -- the majority of her pain on exam occurred in an area of vagina near the right vaginal sulcus, internally in an area where I could palpate scar tissue and an area where her mesh or perhaps at least an edge of mesh may have been located from her prior surgery with Dr. Haverkorn.

Q. Did you recommend any course of treatment for her after your examination?

A. The one thing I did recommend for her was based primarily on her having an elevated post-void residual and talked about ceasing her VESIcare and considering Kegel exercises and/or

biofeedback to help her with her incontinence.

Q. Mrs. Fox also suffered from stress urinary incontinence prior to the implantation of the mesh. Correct?

A. Yes, sir.

Q. That was the reason for having the mesh implant?

A. Yes.

Q. And do you remember her description of her SUI?

A. Based on my report, her complaint was of losing urine -- at least when she presented to Dr. Warner initially or at the women's clinic, I should say, complained of losing urine for the previous year when jumping or sneezing.

Q. This had become a serious problem for her. Correct?

MR. CASPERSON: Object to the form.

THE WITNESS: It was serious enough for her to seek out treatment, yes, sir.

BY MR. OLIVEIRA:

Q. It was a life-altering condition because she couldn't exercise anymore without urinating?

A. Or sneeze, for that matter.

Q. Or sneeze, for that matter.

Are you aware that it appears she got complete relief from her SUI for at least ten years?

A. This is a true comment, yes.

Q. Dr. Walmsley, also in your report, you note that a -- I guess a photograph of the portion of the TVT explanted from Mrs. Fox depicts scar tissue that had become adhered to the TVT as a result of a chronic foreign body response.

What evidence do you have or what basis do you have to support that statement?

MR. CASPERSON: What page are you on?

MR. OLIVEIRA: I have to find it. It was in my notes, but I know it's in his report.

I think the scarring is under -- I'm sorry. We may have to jump back to 3.

MR. CASPERSON: Are you talking about the picture, scar plate?

MR. OLIVEIRA: Yeah.

MR. CASPERSON: Okay.

MR. OLIVEIRA: That's on page --

MR. CASPERSON: That's a good question. It's not numbered.

MR. OLIVEIRA: It's not numbered.

MR. CASPERSON: It's the picture of

the scar plate, Doctor. That's what he's referring to.

MR. OLIVEIRA: Yeah, and I just saw it. I passed it up. Yeah, that's the difficulty. That's why I didn't have it on my --

MR. CASPERSON: I should say the picture of what we allege to be a scar plate.

THE WITNESS: Oh, right.

BY MR. OLIVEIRA:

Q. Did you find that?

A. I did, yes.

Q. Okay. And so my question was, on what basis you made the statement -- let's see.

MR. OLIVEIRA: I'm sorry. Can you read back my question, because I lost my place?

- - -

(The court reporter read the pertinent part of the record.)

- - -

THE WITNESS: There are a couple of elements to the answer.

The first is, I've experienced patients of mine who have had mesh erosion or extrusion events where I've explanted mesh. And unlike in this case where it was submitted to a

pathology off campus, I've submitted it to pathologists here in the hospital and actually looked at the slides with my colleagues and seen chronic inflammation and a foreign body response. That's a fairly classic response to polypropylene mesh.

In addition, I've also in my bibliography have used reports or read reports that describe the response to placement of polypropylene mesh, which inherently is designed to create an inflammatory response and scar tissue in order to provide its desired effect.

Obviously in this instance, the scarring perhaps led to a negative outcome insofar as there was a subsequent complication requiring removal.

BY MR. OLIVEIRA:

Q. In fact, I think you testified, scar tissue formation is a kind of necessary, I guess, for the -- to provide, I guess, integration through the mesh pores. It's a necessary part of the TVT procedure?

A. That's correct.

Q. What's your position -- what's your personal position -- and I believe you testified

before that you have excised or you've removed mesh yourself before. Correct?

A. I have. Yes, sir.

Q. What's your position regarding partial excision as opposed to total recision or removal?

A. I think the majority of revision or excision of mesh procedures are partial, in part because it's extremely difficult to remove all of the mesh. That ends up requiring a significant amount of dissection to do so. And sometimes one can resolve mesh complications with partial excisions.

Q. And do you perform partial excisions?

A. The only mesh excisions I've done have been partial, in fact.

Q. And finally, your last opinion is that "Mrs. Fox's future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded."

What's your basis for saying that?

A. Well, I think there are several things. First off, there's still residual pelvic mesh within her body. And there will be ongoing fibrosis and chronic inflammation relating to that.

Even if the mesh were to be removed in its entirety, that would be an extensive type of surgical procedure, probably restricted to an academic type of center.

Of interest to me during the IME was the amount of discomfort she had when I palpated the area of mesh excision, which supports to me that even in the process of removing mesh, when one is trying to resolve a problem, there are inherent complications of scarring and fibrosis with the partial excision itself.

Q. And what evidence -- when you talk about voiding dysfunction, what evidence of voiding dysfunction have you seen in the medical records?

A. In her particular instance, besides the recurrence of her incontinence, it appears that her incontinence now is not just stress incontinence, it's what we called mixed urinary incontinence, which is a combination of stress incontinence and urgency urinary incontinence. Typically we see that in patients with overactive bladder. She was treated with VESIcare. When I saw her in my office in December, she was on VESIcare, which is an anticholinergenic drug used to treat overactive bladder.

She had had some partial resolution with the VESIcare with relation to her urgency, but not only was the urgency not completely ameliorated, but she had an elevated post-void residual. It was quite high in my office, which supports to me, number one, that the VESIcare is providing perhaps too much of a bladder relaxation effect, number one. And number two, that she is incomplete emptying, which could be related to scarring from her sling procedure or possibly might be related to the VESIcare effect or, thirdly, could be related to some sort of functional disorder of the bladder.

MR. OLIVEIRA: Object to the form.

BY MR. OLIVEIRA:

Q. We've gone through your two general opinions and your five specific opinions in this case.

As we sit here today, do you have any other opinions that you haven't already mentioned or you haven't testified about or that are not contained in your report?

A. No, sir.

MR. OLIVEIRA: I'm going to pass the witness. I know your attorney probably has a few questions, and then I'll -- I'll pass if you have a

few questions. If not...

MR. CASPERSON: We'll reserve for trial.

MR. OLIVEIRA: Okay. Then I will actually recess and just let me look through my notes and make sure. I was going to do that while you were questioning to save some time. I'll do that, so just give me a few minutes.

MR. CASPERSON: Off the record.

- - -

(A recess was taken from 2:03 p.m. to 2:03 p.m.)

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(Deposition Exhibit No. Fox-Walmsley-6, PT Progress Note, was marked for identification.)

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EXAMINATION

- - -

BY MR. CASPERSON:

Q. Dr. Walmsley, I'm handing you what's marked as Exhibit 6 to your deposition.

These are the physical therapy records related to Ms. Fox.

Does that appear to be correct?

A. Yes, sir.
Q. Is this something that you received after your original Rule 26 report was sent?
A. Yes.
Q. Have you had a chance to review those?
A. I did review these, yeah.
Q. Were there any findings in those physical therapist records that are significant in forming your opinions here today?
A. Yes.
Q. What are those findings that you think carry some significance as part of helping you form your opinions?
A. Well, I mean, first off, she continues to have pelvic and vaginal pain.
Secondly, the physical therapist during her exam, while performing a digital exam of the vaginal space, was able to identify discomfort and tenderness in the right aspect of her vagina, consistent with what I found in my IME exam.
Q. Do you believe that to be the same area that you palpated during your IME with Ms. Fox?
MR. OLIVEIRA: Objection, form.
THE WITNESS: Yeah. The same exact

area. Yes.

MR. CASPERSON: I'll pass the witness.

MR. OLIVEIRA: Let me look at those records real quick.

- - -

(A recess was taken from 2:05 p.m. to 2:07 p.m.)

- - -

EXAMINATION

- - -

BY MR. OLIVEIRA:

Q. Doctor, Exhibit Number 6 that your -- Mr. Casperson just questioned you about, these are physical therapy records from a -- it looks like a physical therapy clinic in San Antonio?

A. Yes, sir.

Q. And did it appear to you that -- I guess these are the -- this is just the first segment of treatment that she's going to be getting or first segment of physical therapy?

A. I'm not sure how many segments of physical therapy she's going to receive, but I know she's getting a series of them, yes.

Q. But this doesn't seem to represent a

complete -- that she's completed her whole physical therapy regime here, has she?

A. I don't believe so, no.

Q. So there's a possibility that after she completes however many sessions she's scheduled for -- it looks like it's physical therapy one time a week for 12 weeks -- wouldn't that be a better indication of whether the physical therapy has been helpful?

A. I think it would be helpful for her to complete, yeah, her physical therapy and then to reassess that area.

Q. And wouldn't that be, I guess, a more accurate assessment of what her condition is after she completes the physical therapy?

A. I mean, I hate to be a pessimist. I don't believe there will be much improvement, but there might be some, without question.

Q. Did you see -- going back to the voiding dysfunction, prior to the mesh removal, did you see any mention anywhere in the medical records of voiding dysfunction or urinary incontinence?

A. I did not.

Q. Did you also see that Mrs. Fox reported to Dr. Haverkorn that the SUI, I guess,

she's currently -- has returned but it's not bothersome and that the urgency/frequency is only occasional?

MR. CASPERSON: Object to the form.

THE WITNESS: Her last appointment on April 17th states that she has occasional overactive bladder symptoms with occasional stress incontinence. And at that time she's not on VESIcare.

BY MR. OLIVEIRA:

Q. So that suggests that it hasn't returned to the level it was prior to the surgery, the implantation in 2002. Correct?

A. As far as stress urinary incontinence, yes.

Q. Yes. And that you also are aware that Mrs. Fox has testified that she had complete relief from SUI for the ten years that she had the implant?

A. Correct.

MR. OLIVEIRA: Doctor, I think those are all the questions I have regarding Mrs. Fox. Thank you for your time.

THE WITNESS: Thank you.

(Witness excused.)

(Deposition concluded at approximately 2:11 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, KONSTANTIN WALMSLEY, MD, have the opportunity to read and sign the deposition transcript.

_____

ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 81, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

KONSTANTIN WALMSLEY, MD DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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